Group Art Unit: 3738

Examiner: Pellegrino

Customer No. 26308



Docket No. 9542.18429-FOR

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Macoviak et al.

10/676,815

Serial No.: Filed:

For:

1 October 2003

Devices, Systems, and Methods for Supplementing, Repairing, or Replacing a Native

Heart Valve Leaflet

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN THREE MONTHS OF FILING OR BEFORE MAILING OF FIRST OFFICE ACTION (37 CFR 1.97(b))

"An information disclosure statement shall be considered by the Office if filed: (1) within three months of the filing date of a NOTE: national application; (2) within three months of the date of entry of the national stage as set forth in S 1,491 in an international application; or (3) before the mailing date of a first Office action on the ments, whichever event occurs last." 37 CFR 1.97(b).

The "filing date of a national application" under 37 CFR 1.97(b) has two possible meanings. Where the filing is a direct one NOTE: to the United States Patent & Trademark Office, the filing is defined in 37 CFR 1.53(b) as "the date on which: (1) A specification containing a description pursuant to S 1.71 and at least one claim pursuant to S 1.75; and (2) any drawing required by S 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by S 1.41." 37 CFR 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. S 371(c) within the periods set forth in S 1,494 or S 1,495. 35 U.S.C. S 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 CFR 1.97(b)(2).

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION **DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed WITHIN THREE MONTHS OF THE FILING DATE OF THE APPLICATION OR DATE OF ENTRY INTO THE NATIONAL STAGE OF AN INTERNATIONAL APPLICATION OR BEFORE THE MAILING DATE OF A FIRST OFFICE ACTION ON THE MERITS, WHICHEVER EVENT OCCURS LAST. 37 CFR 1.97(b).

NOTE "NO CERTIFICATION OR FEE IS DUE WHEN THE FILING IS MADE WITHIN THE ABOVE TIME PERIOD. IT IS ADVISABLE TO ENSURE THAT NO OFFICE ACTION HAS BEEN MAILED IF THE DISCLOSURE STATEMENT IS DELAYED UNTIL AFTER THREE MONTHS FROM FILING.

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 CFR 1.8, or Express Mail certificate under 37 CFR 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

CERTIFICATE OF MAILING (37 CFR 1.8(a)) or (37 CFR 1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United State Postal Service on the date shown below as First Class Mail in an envelope addressed as follows: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

Mary Szollar

Type or print name of person mailing paper

(Signature of persol

Date: 16 June 2005

NOTE:

"The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE:

"An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 CFR 1.142) or just a requirement for additional fees to have a claim considered (37 CFR 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING:

"A PETITION FOR SUSPENSION OF ACTION TO ALLOW APPLICANT TIME TO SUBMIT AN INFORMATION DISCLOSURE STATEMENT WILL BE DENIED AS FAILING TO PRESENT GOOD AND SUFFICIENT REASONS, SINCE 37 CFR 1.97 PROVIDES ADEQUATE RECOURSE FOR THE TIMELY SUBMISSION OF PRIOR ART FOR CONSIDERATION BY THE EXAMINER." NOTICE OF JULY 6, 1992 (1141 O.G. 63).

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima face* prior art reference against the claims of the present application.

Should any fees be necessary in connection with this submission, please charge same to Account No. 06-2360.

Date 16 June 2005

Reg. No. 29,243

Telephone No.: (262) 783-1300

Customer No. 26308

Signature of Attorney & Record

Daniel D. Ryan

Type or Print Name of Attorney of Record

RYAN KROMHOLZ & MANION, S.C.

Post Office Box 26618

Milwaukee, Wisconsin 53226-0618

IDS₃

LIST OF PRIOR ART CITED BY APPLICANT	ATTY DOCKET NO. 9542.18429-FOR	SERIAL NO. 10/676,815	
(Use several sheets fracessary)	APPLICANT Macoviak et al.	IDS # 3	
Customer No. 26308	FILING DATE October 1, 2003	GROUP 3738	1/2

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

Davila et al. "Circumferential Suture of the Mitral Ring: A Method For The Surgical Correction of Mitral Insufficiency." Journal of Thoracic Surgery 1955 Nov; 30(5): 531-60.
Harken et al. *The Surgical Correction of Mitral Insufficiency* Journal of Thoracic Surgery. 1954 Dec; 28(6):604-24.
Kuykendall et al. "Surgical Correction of Chronic Mitral Insufficiency in Dogs." Surgery. 1958 Oct; 44(4):718-25.
Harken et al. "The Surgical Correction of Mitral Insufficiency." Surgical Forum 4:4-7 1953.
Davila et al. "A Method For The Surgical Correction of Mitral Insufficiency." Surgery, Gynecology and Obstetrics 1954 Apr; 98(4):407-12.
Davila et al. "The Clinical and Physiologic Criteria For Surgical Correction of Mitral Insufficiency." Journal of Thoracic Surgery 1958 Feb; 35(2):206-31
Glover et al. "The Treatment of Mitral Insufficiency by the Purse-String Technique." Journal of Thoracic Surgery 1957 Jan; 33(1): 75-101.
Rankin et al. "A Clinical Comparison of Mitral Valve Repair Versus Valve Replacement in Ischemic Mitral Regurgitation." J Thorac Cardiovasc Surg. 1988 Feb; 95(2):165-77.
Barnard et al. "A Surgical Approach to Mitral Insufficiency." Br J Surg. 1961 May; 48:655-62.
McKenzie et al. "Current Concepts in Surgical Correction of Acquired Mitral Insufficiency. "Circulation. 1963 Oct; 28:603-16.
Saab et al. "Left Ventricular Aneurysm: A New Surgical Approach." Thorac Cardiovasc Surg. 1989 Feb; 37(1):11-9.
Cicek et al. "Left Ventricular Endoaneurysmorrhaphy: Effect on Left Ventricular Size, Shape and Function." Cardiology. 1997 Jul-Aug; 88(4):340-5.
Liedtke et al. "Functional Reductions in Left Ventricular Volume." J Thorac Cardiovasc Surg. 1976 Feb; 71(2):195-206.
Sosa et al. "Recurrent Ventricular Tachycardia Associated With Postinfarction Aneurysm. Results of Left Ventricular Reconstruction." J Thorac Cardiovasc Surg. 1992 May; 103(5); 855-60.
Cooley, "Repair of Postinfarction Ventricular Septal Defect." J Card Surg. 1994 Jul; 9(4):427-9.
Jatene, "Left Ventricular Aneurysmectomy. Resection or Reconstruction." J Thorqc Cardiovasc Surg 1985; 89:321-31.

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this of with next communication to applicant.

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LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT Macoviak et al.	JUN 2 0 2005	၍ မြS # 3	
Customer No. 26308	FILING DATE October 1, 2003	RADE MADE	GROUP 3738	2/2

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

de Silva et al. "Postinfarction Ventricular Septal Defect. An Efficacious Technique for Early Surgical Repair." J Throac Cardiovasc Surg. 1989 Jan; 97(1):86-9.
Tashiro et al. "Extended Endocardial Repair of Postinfarction Ventricular Septal Rupture: New Opera tive Technique-Modification of the Komeda-David Operation." J Card Surg. 1994 Mar; 9(2):97-102.
Daggett, "Surgical Technique for Early Repair of Posterior Ventricular Septal Rupture." J Thorac Cardiovasc Surg. 1982 Aug;84(2):306-12.
Daggett et al. "Surgery for Post-Myorcardial Infarct Ventricular Septal Defect." Ann Surg. 1977 Sep;186(3):260-71.
Dor, "Left Ventricular Aneurysms: the Endoventricular Circular Patch Plasty." Semin Thorac Cardiovasc Surg. 1997 Apr;9(2):123-30.
Antunes, "Submitral Left Ventricular Aneurysms. Correction by a New Transatrial Approach." J Thorac Cardiovasc Surg. 1987 Aug;94(2):241-5.
Alvarez et al. "Technical Improvements in the Repair of Acute Postinfarction Ventricular Septal Rupture." J Card Surg. 1992 Sep;7(3):198-202.
Cox, "Surgical Management of Left Ventricular Aneurysms: A Clarification of the Similarities and Differences Between the Jatene and Dor Techniques." Semin Thorqc Cardiovasc Surg. 1997 Apr;9(2):131-8.
Skillington et al. "Surgical Treatment for Infarct-Related Ventricular Septal Defects. Improved Early Results Combined with Analysis of Late Functional Status." J thorac Cardiovasc Surg. 1990 May;99(5):798-808.
Salati et al. "Severe Diastolic Dysfunction After Endoventriculoplasty." J Thorac Cardiovasc Surg. 1995 Apr;109(4):694-701.
Yacoub et al. "Anatomic Correction of the Syndrome of Prolapsing Right Coronary Aortic Cusp, Dilatation of the Sinus of Valsalva, and Ventricular Septal Defect." J thorac Cardiovasc Surg. 1997

EXAMINER

DATE CONSIDERED